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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/484,542	06/07/95	BRADER M	X-10097

HM21/1117

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EXAMINER	
ALLEN,M	
ART UNIT	**PAPER NUMBER**
1645	17

DATE MAILED: 11/17/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/484,542	Brader et al.
Examiner	**Group Art Unit**
Marianne P. Allen	1645

☒ Responsive to communication(s) filed on *Aug 21, 1998*.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *25-55* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *25-55* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *14*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Claims 1-12 have been cancelled. Claims 27-55 have been newly introduced. Claims 25-26 and 27-55 are under consideration by the examiner.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's arguments filed 21 August 1998 have been fully considered but they are not persuasive.

Claims 29, 31, 46, 52, and 54-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 is confusing in reciting "further comprising" as claim 28 already possesses a limitation to zinc and claim 29 merely adds a limitation to the amount present.

Claims 31 and 46 are confusing in reciting "5 mg of per milliliter." It appears that a word is missing.

Claim 52 contains a typographical error, "comrpising."

Claim 54 is confusing in reciting "an insulin analog." Claim 42 upon which it ultimately depends already possesses a limitation to an insulin analog. Clarification is requested.

The declaration filed on 21 August 1998 under 37 CFR 1.131 is sufficient to overcome the Baker et al. (U.S. Patent No. 5,693,609) reference with respect to claims 27-35. The declaration is not effective with respect to claims 25-26 and 36-55 for the following reasons. To overcome a reference, the declaration must show either the whole invention or something falling within the claim. (See MPEP 715.02.) The declaration is sufficient for claims 27-35. However, for claims 25-26, the declaration does not show a lyophilized composition nor does the declaration show that this difference would have been obvious to one of ordinary skill in the from the insulin preparation of the declaration. Likewise, for claims 36-37, the declaration does not make clear that a water soluble zinc chloride salt or zinc acetate salt was used. For claims 38-41, the declaration does not address formulations containing normal insulin. For claims 42-55, the declaration does not address formulations of fatty acid-acylated insulin analogs and zinc. Applicant's response makes clear that normal insulin and an insulin analog cannot be equated.

It is noted that the invention claimed in the '609 patent is not the same as the present claimed invention and as such a 1.131 declaration is permissible for the present claims. Zinc is not recited as a limitation in the patent claims. It is further noted that a double patenting rejection does not appear to be merited at this time when the instant claims and '609 claims are compared. However, the '609 patent is still a valid reference for claims 25-26 and 36-55 under 102(e).

Claims 42-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Baker et al. (U.S. Patent No. 5,693,609).

Baker et al. discloses an aqueous formulation of an acylated insulin where zinc is present in the amount of 0.7% (encompassed by the claims as indicated on page 8, lines 12-15). Phenol is present at 30 mM (encompassed by the range set forth in the claim when converted to the corresponding units). (See column 9, lines 10-20.) This formulation is administered to dogs. (See column 9.) The reference is silent as to the pH of the formulation administered. However, absent evidence to the contrary, pharmaceutical formulations are usually administered at or near physiological pH which would be within the range set forth in the claims. The reference further teaches that the formulations may contain mixtures of unacylated insulin or insulin analog in the range of 1:99 to 99:1. (See column 8, lines 48-58.)

The examiner notes applicant's argument that the instant specification narrowly defines "insulin" to be directed to normal or naturally occurring insulin from beef, pork, and human and does not encompass acylated analogs and that the teachings of the '609 patent are directed to acylated analogs and not acylated normal or naturally occurring insulin from beef, pork, and human.

Claims 25-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Havelund et al. (U.S. Patent No. 5,750,497).

Havelund et al. discloses and claims compositions comprising fatty acid acylated insulin and zinc. The claims encompass normal or naturally occurring forms of insulin as defined by the

instant specification as well as analogs. The lysine at position B29 is acylated. The compositions may be aqueous and contain a preservative. The aqueous composition may be between pH 6.5 and 8.5. The composition may contain additional insulin or insulin analogues that are not acylated. (See claims.) The specification indicates that the preservative may be phenol or m-cresol. (See column 15, lines 53-55.) Soluble zinc acetate solution was used. (See Example 28, column 31.) Havelund et al. does not appear to disclose the amount of zinc present in mole/mole terms; however, absent evidence to the contrary, it appears that these limitations would be met. Havelund et al. does not appear to disclose the concentration of the phenolic compound present; however, absent evidence to the contrary, it appears that these limitations would be met. Havelund et al. does not appear to disclose the mole ratio of acylated to unacylated components; however, absent evidence to the contrary, it appears that these limitations would be met given the broad range presently claimed.

Applicant is reminded that a 1.131 declaration is not proper where the prior art is a patent claiming the same invention as applicant. If the effective filing date of the application is more than 3 months after the effective filing date of the patented application, the applicant must comply with 1.608(b). See MPEP 2306-2307 and 2308.01-2308.02.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen, whose telephone number is (703) 308-0666. The examiner can normally be reached on Monday-Friday from 9:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached on (703) 308-3995. Official FAX communications may be directed to either (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Marianne P. Allen

MARIANNE P. ALLEN
PRIMARY EXAMINER
~~GROUP 1800~~
AU1645